## REMARKS

Upon entry of this amendment, claims 38-40, 44-46, 48-50, 54, 56-59, and 62-69 will be pending in the application. Claims 1-37, 41, 42, 43, 47, 51, 52, 53, 55, 60, and 61 are canceled. Claims 38, 44, 45, 46, 56, and 59 are amended. New claims 63-69 are added. Exemplary support for the new claims is provided in Figure 4 and at pages 52-53 of the specification. No new matter is introduced by this amendment.

The specification is amended to update the priority claim and to provide sequence identifiers for the description of Figure 3. Support for the amendment of the description of Figure 3 is located on page 51, lines 24-29 of the specification as filed. No new matter is introduced by this amendment.

***The specification does not contain new matter.***

Original claims 8 and 9 of the present application support the amendment of the paragraph bridging pages 3-4 filed July 8, 2003. Withdrawal of the new matter rejection on that basis is respectfully requested.

***Obviousness-type double patenting***

Claims 38-44, 49-54, 55, 59, and 62 are rejected for alleged obviousness-type double patenting over claims 49 and 40 of co-pending U.S. Application Serial No. 11/580,632, filed October 11, 2006. MPEP § 804.I.B provides that, where a "provisional" nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of two pending applications, "the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." As the present application is the earlier filed application, upon resolution of other grounds of rejection, the obviousness-type double patenting rejection over U.S. Application Serial No. 11/580,632 should be withdrawn and the present application allowed to issue without a terminal disclaimer.

Claims 38-44, 49-54, 55, 59, and 62 are rejected for alleged obviousness-type double patenting over claims 1, 3, 4, 6, and 7 of U.S. Patent No. 6,090,611. Applicants respectfully

request that the rejection be held in abeyance pending notification of allowable subject matter in the present application.

***Claim 46 is directed to statutory subject matter under section 101.***

Claim 46 is rejected under section 101 for being directed to alleged nonstatutory subject matter. Without conceding the propriety of the rejection and in an effort to advance prosecution, Applicants have amended claim 46 to recite an "isolated" cell. The claimed cell does not read on naturally occurring *H. pylori* containing the CAI gene because the CAI gene is in the genome rather than on a vector as presently claimed and genomic DNA would not be confused by one of skill in the art with vector DNA. Withdrawal of the rejection is respectfully requested.

***Claims 48, 56-59, and 62 do not contain new matter.***

Claims 41, 42, 48, 51, 52, 56, 57, 58, 59, and 62 are rejected under the first paragraph of section 112 for allegedly containing new matter. Without conceding the propriety of the rejection, claims 41, 42, 51, and 52 are canceled. Claim 48 recites a polynucleotide comprising at least 15 contiguous nucleotides from nucleotide position 2776 to nucleotide position 3466 of the nucleotide sequence of SEQ ID NO:4. Claim 57 recites a polynucleotide encoding at least amino acid positions 748 to 977 of the amino acid sequence of SEQ ID NO:5. Exemplary support for the claims is provided by Figure 3, clones G5 and A17, corresponding to nucleotides 2776 to 3466 of SEQ ID NO:4 and amino acids 748-977 of SEQ ID NO:5, and by page 12, lines 8-11. Claim 58 recites a polynucleotide comprising the contiguous nucleotides from nucleotide position 535 to nucleotide position 3975 of the nucleotide sequence of SEQ ID NO:4 as supported by the open reading frame illustrated in Figure 4. Claim 62 recites a polynucleotide comprising at least one nucleotide sequence of nucleotides 3172-3189 of SEQ ID NO:4, nucleotides 3202-3216 of SEQ ID NO:4, nucleotides 3259-3273 of SEQ ID NO:4, nucleotides 2641-2676 of SEQ ID NO:4, or nucleotides 2776-2811 of SEQ ID NO:4. The nucleotide regions recited by the claim are the nucleotide sequences corresponding to the boxed amino acid regions illustrated in Figure 4. Amended claims 56 and 59 recite polynucleotides encoding a Helicobacter pylori CAI antigen immunologically identifiable with the amino acid sequence of SEQ ID NO:5.

Exemplary support for the claims is located in the specification on page 14, lines 21-30. Withdrawal of the rejection is respectfully requested as the claims are fully supported by the specification.

***Claims 38, 44, 56, and 59 are fully enabled by the specification.***

Claims 38, 41-44, 51-53, 56, and 59 are rejected under the first paragraph of section 112 for alleged lack of enablement. In an effort to advance prosecution and without conceding the propriety of the rejection, claims 41-43 and 51-53 are canceled, and claims 56 and 59 have been amended to omit the terms "immunogenic fragment" and "immunogenic derivative." To the extent the rejection is maintained against the claims as amended herein, Applicants traverse.

The standard for enablement is whether the skilled artisan can make and use the disclosed invention without undue experimentation. MPEP § 2164.01. An inventor need not enable every mode of making and using the invention, and the enablement requirement is fulfilled if any mode of making and using the invention is described. *Engel Industr. v. Lochformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991) ("[t]he enablement requirement is met if the description enables any mode of making and using the invention")(emphasis added); see also *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) ("Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.").

In making a determination of enablement, the inquiry is not whether experimentation is required, but rather whether the experimentation required is undue. According to the Federal Circuit, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed . . . ." *In re Wands,* 858 F.2d 731, 737 (Fed. Cir. 1988) (citations omitted). In *In re Wands*, eight factors to be considered in assessing whether a disclosure is enabling were elucidated: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the

presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Thus, a patent claim is invalid for lack of enablement in instances in which consideration of the *Wands* factors leads to a conclusion that practice of the invention would require undue experimentation.

In the present case, the skill in the art of immunology is high and the state of that art is sufficiently developed such that one skilled in the art, armed with the detailed teachings of the present specification and the working examples provided therein, would be able to make and use the presently claimed invention with no more than routine experimentation.

The present claims are directed to polynucleotides comprising at least 15 contiguous nucleotides from the nucleotide sequence of SEQ ID NO:4, wherein the polynucleotide comprises at least one nucleotide sequence encoding the amino acid sequence of SEQ ID NO:10, and polynucleotides encoding at least five contiguous amino acids from the amino acid sequence of SEQ ID NO: 5, wherein the polynucleotide comprises at least one nucleotide sequence encoding the amino acid sequence of SEQ ID NO:10. Applicants illustrate SEQ ID NO:4 and SEQ ID NO:5 in Figure 4. The breadth of the claims is thus consistent with the enabling disclosure of the specification and the examples provided therein in view of the knowledge in the art.

The specification provides detailed guidance and working examples regarding methods of making and using the claimed polynucleotides. Applicants have exemplified several ELISA assays employing polynucleotides falling within the claims on pages 54-55 of the specification. For example, Applicants demonstrated use of a fusion protein of clone A17 fragment in an ELISA assay using sera of patients with gastroduodenal disease. Applicants note that the present claims do not require *H pylori* CAI polypeptide immunospecificity or therapeutic or prophylactic activity. Applicants have taught those of skill in the art how to make and use polynucleotides in accordance with the present claims. One skilled in the art would be able to predictably reproduce and use the polynucleotides demonstrated and now claimed by the Applicants with no more than routine experimentation in view of the guidance provided by the specification and the knowledge and skill in the art.

As Applicants have taught those of skill in the art how to make and use the claimed polynucleotides without undue experimentation, withdrawal of the rejection is respectfully requested.

***Amended claims 45, 46, 56, and 59 would be understood by those skilled in the art.***

Claims 41-43, 45, 46, 51-53, 56, and 59 are rejected under the second paragraph of section 112 for alleged lack of clarity. Claims 41-43 and 51-53 are canceled.

Claims 56 and 59 are rejected under the second paragraph of section 112 for alleged lack of clarity in recitation of the terms "immunogenic fragment" and "immunogenic derivative." Without conceding the propriety of the rejection, and in an effort to advance prosecution of the application, Applicants have amended claims 56 and 59 to omit the terms.

Claim 45 is amended to recite "claim 38 or 44."

Claims 56 and 59 are rejected for alleged lack of clarity in recitation of the phrase "immunologically identifiable." One skilled in the art would understand that term in the context of its use in the present specification to mean that one peptide is recognized by the same antibody which recognizes a reference polypeptide. For example, Helicobacter pylori CAI antigen that is immunologically identifiable with the amino acid sequence of SEQ ID NO:5 is a polypeptide that is bound by an antibody that binds the polypeptide of SEQ ID NO:5. Withdrawal of the rejection is respectfully requested.

Claim 46 is amended to provide clear antecedent basis.

Withdrawal of the rejections under the second paragraph of section 112 is respectfully requested.

***Claims 38-40, 44-46, 48-50, 59, and 62 are not anticipated by U.S. Patent No. 5,403,924.***

Claims 38-40, 44-46, 48-50, 59, and 62 are rejected under section 102(e) for alleged anticipation by U.S. Patent No. 5,403,924 to Cover *et al.* In an effort to advance prosecution of the application and without conceding the propriety of the rejection, claims 41-43, 47, 51-53, 55, 60, and 61 have been canceled. Claims 38 and 44 are amended to omit SEQ ID NO:9. Withdrawal of the rejection is respectfully requested in view of the amendments.

## CONCLUSION

Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the undersigned may be contacted at 215.564.8978.

Respectfully submitted,

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